UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,622	01/17/2006	Judy Lieberman	033393-055194	1754

50828 7590 01/22/2009

DAVID S. RESNICK
NIXON PEABODY LLP
100 SUMMER STREET
BOSTON, MA 02110-2131

EXAMINER	
PITRAK, JENNIFER S	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
01/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

bostonpatent@nixonpeabody.com
mstembridge@nixonpeabody.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,622	LIEBERMAN ET AL.	
	Examiner	Art Unit	
	JENNIFER PITRAK	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-99* is/are pending in the application.

4a) Of the above claim(s) *73,76,77 and 84-99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72,74,75 and 78-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/13/2007; 04/10/2006; 09/19/2005..

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 72, 74, 75, and 78-83 in the reply filed on 11/20/2008 is acknowledged. The traversal is on the ground(s) that Group III and Group VII have the same or corresponding special technical feature, namely siRNAs against FAS, and that no prior art was set forth in the Requirement for Restriction/Election (mailed 05/21/2008) teaching siRNAs against FAS. This is not found persuasive because the special technical feature among all of the groups is apoptosis-related siRNA. Furthermore, siRNAs against FAS are taught in the prior art as indicated in the following rejections.

The requirement is still deemed proper and is therefore made FINAL.

Claims 73, 76, 77, and 84-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/20/2008.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or

provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/422,578, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 60/422,578 does not provide support for lentiviral vectors. Therefore, claim 81 is accorded priority only to the filing date of the instant application, which is 10/30/2003. Claims 72, 74, 75, 78-80, 82, and 83 are accorded priority to the filing date of Application No. 60/422,578, which is 10/30/2002.

Specification

The disclosure is objected to because of the following informalities:

Applicant's attention is directed to the attached Notice to Comply with 37 C.F.R. 1.821 - 1.825. The sequences on pages 56-57 of the specification, SEQ ID NOs: 1-16, do not match the sequences of the Sequence Listing. Appropriate correction is required. If a new (substitute) "Sequence Listing" is required to correct this discrepancy, then Applicant must also provide a substitute CRF copy of the "Sequence Listing", a substitute paper copy of the "Sequence Listing", an amendment directing the entry of the substitute paper copy of the "Sequence Listing" into the specification, and a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

The tables are not consecutively numbered (see Table 2 on page 35 and Table I on page 72). Appropriate correction is required.

To be considered fully responsive, any reply to this action must address these deficiencies, as this requirement will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 72, 74, and 75 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu, et al. (2002, J. Biol. Chem, v.277:26281-5).

The claims are to an siRNA agent that inhibits expression of an apoptosis-related gene and is homologous to an apoptosis-related gene, or a fragment thereof.

Liu, et al. teach siRNAs that inhibit expression of *DIP13α* (abstract; p.26282, bottom of first column; p.26284, bottom of first column). Therefore, Liu, et al. anticipate the instant claims.

Claims 72, 74, 75, 80, 82, and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Finger, et al. (U.S. Patent Application Publication 2003/0157514, filed as provisional Application no. 60/317,063 on 9/4/2001) (Finger).

The claims are to an siRNA agent that inhibits expression of an apoptosis-related gene and is homologous to an apoptosis-related gene, or a fragment thereof. The claims are further to retroviral vectors and host cells comprising a DNA encoding the siRNA agent.

Finger teaches siRNAs targeting and inhibiting the expression of the apoptosis-related gene, PMN29 (page 6, paragraph 0079; page 9, paragraph 0106; page 11, paragraph 0123, page 14, paragraphs 0158-0160). Finger also teaches that the siRNAs can be incorporated into retroviral vectors and into host cells (page 46, paragraphs 0391; page 51, paragraphs 0430-0431; page 64, paragraphs 0551-0553). Thus, Finger clearly anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 72, 74, 75, 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finger (above) as evidenced by Pandya, et al. (2001, Exp. Opin. Biol. Ther., v.1:17-40) (Pandya).

Claims 72, 74, 75, 80, 82, and 83 are described above. Claim 81 specifies that the vector is a lentiviral vector.

Finger teaches siRNAs targeting the apoptosis-related gene, PMN29, which inhibit PMN29 expression (page 6, paragraph 0079; page 9, paragraph 0106; page 11, paragraph 0123, page 14, paragraphs 0158-0160). Finger also teaches retroviral vectors and host cells comprising the siRNAs (page 46, paragraphs 0391; page 51, paragraphs 0430-0431; page 64, paragraphs 0551-0553). Finger teaches HIV as a vector available for expressing polynucleotides encoding polypeptides (page 61, paragraph 0517). Finger does not teach HIV or a lentivirus as a vector for expressing DNA encoding siRNAs. HIV is a lentiviral vector, as evidenced by Pandya (page 19, end of first paragraph).

It would have been obvious to one of skill in the art at the time the invention was made to make siRNAs in retroviral vectors as taught by Finger. It further would have been obvious to use HIV as the retroviral vector comprising the siRNAs because Finger teaches HIV vectors as retroviral expression vectors for expressing polypeptides. One of skill in the art would immediately recognize HIV as a retroviral vector also available for siRNA expression because Finger teaches the use of retroviral vectors for siRNA expression and Finger teaches HIV as one type of retroviral expression vector. Thus, the claims would have been obvious at the time of the invention.

Claims 72, 74, 75, 78, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean, et al. (2001, U.S. Patent 6,204,055) (Dean) and Elbashir, et al. (2001, Nature, v. 411:494-8) (Elbashir).

The claims are to Fas- or FasL-targeted siRNAs.

Dean teaches Fas- and FasL-targeted antisense oligonucleotides (paragraphs 21 and 35). Dean does not teach Fas- and FasL-targeted siRNAs.

Elbashir teaches siRNAs that suppress expression of genes, provide a new tool for studying gene function in mammalian cells, and may be used as gene-specific therapeutics (abstract; first column on page 495; Figure 1). Elbashir teaches that siRNAs are extraordinarily powerful reagents for mediating gene silencing, and that siRNAs are effective at concentrations that are several orders of magnitude below the concentrations applied in conventional antisense experiments (p. 496, first paragraph).

It would have been obvious to one of skill in the art to make Fas- or FasL-targeted antisense oligonucleotides as taught by Dean. It further would have been obvious to substitute Fas- or FasL-targeted siRNAs as taught by Elbashir for the antisense oligonucleotides of Dean because Elbashir teaches that siRNAs are more effective than antisense oligonucleotides. One of skill in the art would expect that substituting siRNAs for antisense oligonucleotides would likely yield better Fas or FasL gene inhibition than the inhibition achieved with antisense oligonucleotides. Thus, the claims would have been obvious at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak
Examiner
Art Unit 1635

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635